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09/761,167	01/12/2001	Joseph Kevin Gogerty	PO4813USO PHI 1315	4720

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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

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10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. 09/76,167	Applicant(s) Gogerty	
Examiner FOX	Group Art Unit 1638	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/11/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-8, 20, 33-54 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 1-7, 20, 41-43, 46 is/are allowed.
- ☒ Claim(s) 8, 33-40, 44, 45, 47-54 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 11 March 2003 has overcome the outstanding indefiniteness rejections of all claims except claim 8 as set forth on page 3 of the last Office action, and the art rejection of record.

Claims 37-40, 47, 48 and 54 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 37 and dependents have been amended to recite the term "backcross conversion 35Y54 hybrid maize plant". Claim 47 has been amended to recite a double haploid method. Claim 48 has been amended to recite "inbred line comprises at least about 75% genetic identity to". Claim 54 has been amended to recite "the pedigree of said 35Y54 progeny maize plant has 2 or less breeding crosses to a plant other than 35Y54". There is no literal basis in the specification for any of these terms.

Claim 8 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated in the last Office action on page 3 for claims 8 and 21.

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Claims 34-35 and 38-40 (newly submitted) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-35, drawn to a maize plant, are confusing in their dependence upon claim 33, drawn to a method. Similarly, claims 38-40, drawn to a maize plant, are confusing in their ultimate dependence upon claim 37, drawn to a method. Replacement of "maize plant" with --method-- in each of claims 34-35 and 38-40 would obviate this rejection.

Claims 33-40, 45 and 48 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney

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of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Specifically, the deposit conditions for the newly recited two inbred parental lines are unclear.

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Claims 8, 33-35, 37-40, 44 and 47-54 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-5 of the last office action for claims 8-19 and 21-32.

Claims 8, 33-35, 37-40, 44 and 47-54 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 5-8 in the last Office action for claims 8, 12-19, 21, and 25-32.

The claims are deemed free of the prior art, as stated on page 8 of the last Office action. In addition, the prior art fails to teach or fairly suggest plants which are produced by crossing the exemplified parental inbreds or inbreds which are 75% genetically identical thereto, or progeny plants which are within two outcrosses of the exemplified hybrid.

Claims 1-7, 20, 41-43 and 46 are allowed.

Applicant's arguments filed 11 March 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the indefiniteness rejection is improper, given the disclosure in the specification of "manipulations of cytoplasmic or other factors" for male sterility. The Examiner maintains that the introduction of a different cytoplasm than the one originally found in the plant

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of claim 2 would render the male sterile plant of claim 8 genetically different than the plant of claim 2. In addition, "other factors" encompasses nuclear genes for male sterility, as evidenced by the specification on page 2, line 9, in the recitation of "genetic male sterility". Thus, claim 8 fails to further limit claim 2. It is noted that the proposed amendment faxed by Supervisory Patent Examiner Amy Nelson recited a detasseled plant of claim 2, wherein said detasseled plant would be genetically identical to the plant of claim 2.

Applicant urges that the written description rejection is improper, given the guidance in the specification regarding available transgenes and methods for their introduction, the ability of a deposit to provide such a description as taught by *Enzo*, and the submission of method claims in the same format as suggested by the Examiner and his supervisor.

Regarding the recitation of transgenes, the Examiner maintains that claims limited to the particularly recited transgenes would be adequately described, but that claims broadly drawn to any transgene as recited in claim 33, including those conferring any "value-added trait" as recited in claims 34 and 38, and any "derivative" or synthetic polypeptide-encoding gene as recited in claims 35 and 39, are not. The specification provides no guidance regarding all transgenes, any "value-added trait gene", or any "derivative" or "synthetic" *B. t.* gene or encoded protein. In addition, the specification provides no guidance for any conserved sequences found in all transgenes, conserved sequences found in all "value-added trait genes", or conserved sequences found in all "derivatives" or "synthetic" insecticidal toxin genes; or any correlation of any putative conserved sequences with function; as required by the Revised Written Description

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Guidelines, Federal Register Vol. 66, No. 4, issued Friday, January 5, 2001, pages 1099-1111.

See also MPEP 2163.

Amendment of claim 33 to incorporate claim 34 and to replace “and value added trait gene” with --a gene conferring modified fatty acid or carbohydrate metabolism, and a phytase gene-- would obviate this rejection for claim 33. Amendment of claims 34 and 38 to replace the phrase “and value-added trait gene” with the phrase above would obviate the rejection of these claims. Amendment of claims 35 and 39 to delete “, a derivative thereof or a synthetic polypeptide modeled thereto” would obviate the rejection of those claims.

Regarding *Enzo*, the Examiner maintains that while claims limited to the deposited hybrid are adequately described, claims broadly drawn to any other variant or descendant thereof containing additional genes are not. Note that the Federal Circuit in *Enzo* remanded the case to the District Court to decide this issue. Furthermore, the Examiner has demonstrated that the introgression of a gene of interest would in fact result in the introduction of additional, uncharacterized genetic material.

Furthermore, the Examiner maintains that no attempt was made to genetically characterize the exemplified hybrid at any particular genetic locus. The hybrid was only characterized based upon the collection of particular traits, wherein the individual traits were not unique to the claimed hybrid either in genetic control or level of expression. In the absence of any characterization of the genotype of the exemplified hybrid, progeny plants containing even half of its genome are also inadequately described. In addition, plants containing even 100% of the



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hybrid genome, but with a multitude of allelic rearrangements and reassortments at each locus due to selfing (see claims 50 and 52) are also inadequately described, since it is unclear what traits this plant would exhibit, and since it is unclear whether each locus contains a dominant allele or recessive allele, in the absence of the genetic characterization of the exemplified hybrid at even one locus.

Applicant is further directed to pages 6-7 of the specification, where it is taught that there are between 10-1000 genes in maize which affect agronomic traits, wherein only one plant of a particular genotype in 10,000 progeny in the F2 generation is agronomically useful, and wherein a single agronomically useful genotype exists in progeny with only a  $10^{-5}$  probability or lower. Thus, progeny claims read on at least  $10^5$  individuals, none of whom have been adequately described.

Regarding the method claims, the Examiner notes that new claims 37-40 are drawn to methods of backcrossing, new claims 49 and 51 are drawn to methods of crossing the exemplified hybrid for multiple generations, and new claim 53 is drawn to methods of outcrossing with any other parent for an unspecified number of generations. All of these methods were deemed unsupported by an adequate written description in the last Office action.

Applicant urges that the enablement rejection is improper, given the failure of the references cited by the Examiner to actually support his position. Applicant urges that Hunsperger et al do teach some successes, that the instant specification suggests the construction of genetic maps, and that Kraft et al do not teach the general unpredictability inherent in the

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process. The Examiner maintains that Hunsperger et al teach failures as well as successes, while Applicant does not attempt or reduce to practice any single gene conversion. Kraft et al do teach the unpredictability inherent in constructing genetic maps based upon molecular marker data, even when the parent plants are adequately characterized, thus refuting Applicant's assertions that such maps may be constructed here. Furthermore, it is noted that the instantly exemplified hybrid is NOT adequately characterized, as stated above, and that none of the other non-exemplified parents embraced by the broad claims are characterized at all. In addition, Applicant has admitted on pages 6-7 of the specification that only one in at least 10, 000 progeny plants would be agronomically useful. The specification has not provided any guidance as to the recovery or identification of this single plant, or as to methods of using the other 10,000 plants.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 29, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in black ink, appearing to read 'David T. Fox', is written over the printed name and title.